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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,319	08/24/2001	Kosuke Seiki	11283-014001	2187

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FISH & RICHARDSON P.C.
45 ROCKEFELLER PLAZA, SUITE 2800
NEW YORK, NY 10111

EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	4

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,319	SEIKI ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Objections

1. Claims 1 – 7 are objected to because of the following informalities: Claim 1 recites the abbreviation "L-PGDS" without first reciting the limitation in full. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1 – 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependents are rendered vague and indefinite because the claim appears to omit essential steps to the method. For example, the claims are drawn to a method for predicting restenosis by measuring L-PGDA concentration, but fail to include what measurements indicate a prediction of restenosis (i.e. a high concentration, low concentration). Moreover, it is unclear how simply measuring L-PGDA predicts restenosis.

Claims 2 and 3 are vague because it is unclear what type of change indicates a prediction of restenosis.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 – 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Eguchi et al. (1997, Proc. Natl. Acad. Sci.).

Applicant claims a method for predicting restenosis following coronary intervention, the method comprising measuring lipocalin-type prostaglandin D synthase (L-PGDS) in a body fluid. Specifically, a change in L-PGDS concentration after coronary intervention is used as an indicator or a change in L-PGDS concentration before and after coronary intervention is used as an indicator. The L-PGDS concentration is measured using an immunological measuring method, the body fluid is blood or urine and the blood taken from coronary or peripheral blood. Finally, the coronary intervention is PTCA, DCA, TEC, Rotablator, excimer laser coronary angioplasty or intracoronary stenting.

Eguchi teaches methods wherein coronary and peripheral blood samples taken before and after PTCA are measured for L-PGDS concentration via immunoassay (14690, left). Although Eguchi does not specifically teach the steps wherein restenosis is predicted, the method steps are the same. Therefore, by practicing the method of Eguchi, one would have inherently practiced the method as claimed.

Therefore, the reference anticipates the claimed subject matter.

6. Claims 1 – 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Oda et al. (WO 98/49559).

Applicant claims a method for predicting restenosis following coronary intervention, the method comprising measuring lipocalin-type prostaglandin D synthase (L-PGDS) in a body fluid. Specifically, a change in L-PGDS concentration after coronary intervention is used as an indicator or a change in L-PGDS concentration before and after coronary intervention is used as an indicator. The L-PGDS concentration is measured using an immunological measuring method, the body fluid is blood or urine and the blood taken from coronary or peripheral blood. Finally, the coronary intervention is PTCA, DCA, TEC, Rotablator, excimer laser coronary angioplasty or intracoronary stenting.

Oda teaches methods for predicting ischemic diseases by measuring L-PGDS in body fluids (abstract). Specifically, Oda teaches a method wherein coronary and peripheral blood is collected before and after PTCA, and is measured for L-PGDS via immunoassay (example 4). Oda teaches that such methods enable prognosis, or prediction of ischemic conditions (example 4). Although Oda does not specifically name restenosis as the ischemic condition, it was a well known ishcemic condition in the art.

Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1 – 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eguchi et al.

Applicant claims a method for predicting restenosis following coronary intervention, the method comprising measuring lipocalin-type prostaglandin D synthase (L-PGDS) in a body fluid. Specifically, a change in L-PGDS concentration after coronary intervention is used as an indicator or a change in L-PGDS concentration before and after coronary intervention is used as an indicator. The L-PGDS concentration is measured using an immunological measuring method, the body fluid is blood or urine and the blood taken from coronary or peripheral blood. Finally, the coronary intervention is PTCA, DCA, TEC, Rotablator, excimer laser coronary angioplasty or intracoronary stenting.

Eguchi teaches methods wherein coronary and peripheral blood samples taken before and after PTCA are measured for L-PGDS concentration via immunoassay (14690, left).

Eguchi does not specifically teach the method wherein restenosis is predicted. However, Eguchi does teach that acute occlusion (or restenosis) often happens within several hours of PTCA when L-PGDS levels are decreasing in the cardiac vein (14693, right) whereas restenosis hardly occurs several days after PTCA when L-PGDS levels have increased (14693, right). In addition, Eguchi reports that patients with normal coronary angiography demonstrate little to no difference in L-PGDS concentration between cardiac artery and vein, while those with stenosis demonstrate a significantly higher L-PGDS concentration in the cardiac vein (14691, right). Moreover, Eguchi teaches that L-PGDS accumulates in patients with stenosis (14691, right).

At the time of the claimed invention, one of ordinary skill in the art would have been motivated by the teachings of Eguchi to practice the method with a reasonable expectation for predicting restenosis.

10. Claims 1 – 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oda et al.

Applicant claims a method for predicting restenosis following coronary intervention, the method comprising measuring lipocalin-type prostaglandin D synthase (L-PGDS) in a body fluid. Specifically, a change in L-PGDS concentration after coronary intervention is used as an indicator or a change in L-PGDS concentration before and after coronary intervention is used as an indicator. The L-PGDS concentration is measured using an immunological measuring method, the body fluid is blood or urine and the blood taken from coronary or peripheral blood.

Finally, the coronary intervention is PTCA, DCA, TEC, Rotablator, excimer laser coronary angioplasty or intracoronary stenting.

Oda teaches methods for predicting ischemic diseases by measuring L-PGDS in body fluids (abstract). Specifically, Oda teaches a method wherein coronary and peripheral blood is collected before and after PTCA, and is measured for L-PGDS via immunoassay (example 4). Oda teaches that such methods enable prognosis, or prediction of ischemic conditions (example 4).

Oda does not specifically teach the method wherein restenosis is the ischemic condition predicted. However, at the time of the claimed invention, it was well known in the art that restenosis is an ischemic condition. In support, Scarborough (US 5807828) teaches ischemic syndromes include restenosis (col.1 line 24-34). Therefore, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to practice the methods of Oda with a reasonable expectation for successfully predicting restenosis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad
February 5, 2003

LEON B. LANKFORD, JR.
PRIMARY EXAMINER